AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/589,495

REMARKS

Claim 1 has been amended to recite the features of canceled claim 20 and to recite "wherein said C-terminal amino acids are degraded with alkanoic anhydride, without a perfluoroalkanoic acid or the anhydride thereof, in said step of obtaining C-terminal-deleted peptides." Support may be found, for example, on page 8, line 27 to page 9, line 3 and page 5, lines 11-23 of the specification. Claims 5 and 14-16 have been amended to address informalities noted by the Examiner.

No new matter has been introduced. Entry and consideration of the amendments are respectfully requested.

Response to Claim Objections

Claim 5 is objected to because it recites "my" instead of "by." Claim 5 has been amended to recite "wherein said C-terminal amino acids are degraded by making said peptide substantially bring into contact with an alkanoic anhydride in said obtaining C-terminal-deleted peptides." Reconsideration and withdrawal of the objection are respectfully requested.

Response to Rejection under 35 U.S.C. § 112, first paragraph - enablement

Claims 14-18 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly is not enabling for obtaining the C-terminal-deleted peptide retained in a gel (or for processing the sample in the gel) under any other reaction conditions besides using a dipolar aprotic solvent, which is disclosed on pages 41-42 of the specification.

Applicants submit that the specification is enabling for the method as claimed. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. Failure to disclose other methods by which the claimed invention

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may be made does not render a claim invalid under 35 U.S.C. 112. MPEP 2164.01(b). Here, the specification discloses and describes how to use the recited method on pages 41-42 of the specification. Further, the specification discloses and describes how to use solvents such as polar aprotic solvents and hydrophobic solvents and provides examples of such including "nitrile of 4 or less carbons" and "ketones having 4 or less carbon atoms" (page 36, lines 19-26).

Reconsideration and withdrawal of the rejection are respectfully requested.

Response to Rejection under 35 U.S.C. § 112, second paragraph - indefiniteness

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Examiner states that the claims recite "the gel," which lacks antecedent basis. The Examiner further states that claims 15 and 16 recite "the processings," which lack antecedent basis.

Applicants have amended claims 14-16 to each recite "a gel" rather than "the gel" to address the Examiner's concerns.

Applicants have amended claims 15 and 16 to recite "said obtaining" and "said obtainings" to address the Examiner's concerns.

With regard to the Examiner's question on page 3 of the Office Action, Applicants submit that the claimed C-terminal-deleted peptides and C-terminal-deleted peptide-derived peptide fragments may be "obtained" while still in a gel because presence in a gel does not preclude obtainment within the scope of the invention. For example, Applicants describe the sequential degradation of the C-terminal (step S113) in a gel in the First Embodiment (page 37, line 13 to page 39, line 10; page 44, line 25 to page 45, line 7; see also Fig. 5). The Examiner must analyze the definiteness of claim language in light of Applicants' disclosure, the teaching of the prior art, and the claim interpretation of a skilled artisan. MPEP 21743.02.

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Reconsideration and withdrawal of the rejection are respectfully requested.

Response to Rejections under 35 U.S.C. § 102

A. Claims 1-4, 22, and 23 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tsugita et al. (Electrophoresis, 1998) ("Tsugita").

In view of the amendment to claim 1 incorporating the features of canceled claim 20, Tsugita does not teach each and every feature of claims 1-4, 22, and 23.

Reconsideration and withdrawal of the rejection are respectfully requested.

B. Claims 1-10, 12-16, 18-19, and 22-23 are rejected under 35 U.S.C. § 102(a) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Miyazaki et al. (Seikagaku, 2003, IDS) ("Miyazaki").

In view of the amendment to claim 1 incorporating the features of canceled claim 20, Miyazaki does not teach each and every feature of claims 1-10, 12-16, 18-19, and 22-23.

Also, Applicants concurrently submit a Declaration under 37 C.F.R. § 1.132 stating that Miyazaki is Applicants' own work. See MPEP 715.01(c).I. The Declaration is sufficient to remove Miyazaki as a reference under 35 U.S.C. § 102(a).

Reconsideration and withdrawal of the rejection are respectfully requested.

Response to Rejections under 35 U.S.C. § 103

Claims 1-10, 12-16, 18-19, and 22-23 are rejected under 35 U.S.C. § 102(a) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Miyazaki.

Regarding claim 1, Miyazaki is cited as teaching the step of obtaining the claimed peptides (abstract); and measuring the molecular weight (abstract); wherein the C-terminal amino acids are degraded by making the peptide in contact with acetic anhydride (abstract).

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The Examiner acknowledges that Miyazaki does not teach determining the decrease in molecular weight but contends that calculating the molecular weight difference is an inherent part of the method. The Examiner states, in the alternative, that it would have been obvious to determine the molecular weight difference to derive the deleted amino acid.

Regarding claim 5, Miyazaki is cited as teaching the steps of claim 1 and further teaching cleaving C-terminal-deleted peptide at predetermined position by trypsin and measuring the molecular weight of C-terminal-deleted peptide-derived peptide fragments (abstract). The Examiner applies a similar analysis alleging inherency and, in the alternative, obviousness of the claimed step of determining the decrease in molecular weight.

All of the remaining rejections under 35 U.S.C. § 103 for obviousness rely on either Tsugita or Miyazaki as a primary reference. Namely, claims 5 and 6 are rejected over Tsugita; claims 7-13 are rejected over Tsugita in view of Covey; claim 11 is rejected over Miyazaki in view of Covey; claims 14-16, 18, and 19 are rejected over Tsugita in view of Vogt; claim 17 is rejected over Tsugita in view of Vogt and further in view of Wirth; claim 17 is rejected over Miyazaki in view of Wirth; and claims 20-21 are rejected over Tsugita in view of Zeldin.

Applicants respond as follows:

Preliminarily, Tsugita does not teach each and every feature of amended claim 1 (and dependent claims 5, 6, 7-13, 14-16, 17, 18, 19, and 21), and none of Covey, Vogt, Wirth, and Zeldin cure the deficiencies of Tsugita.

Also, Miyazaki is Applicants' own work, so Miyazaki is removed as a reference under 35 U.S.C. § 102(a). Therefore, Miyazaki may not be relied upon to support a finding of obviousness.

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Even if Miyazaki were in the prior art—which it is not—Miyazaki is deficient as follows.

Miyazaki does not teach "wherein said obtaining the C-terminal-deleted peptides is carried out in a system containing a basic nitrogen-containing aromatic ring compound" and

"wherein said C-terminal amino acids are degraded with alkanoic anhydride, without a perfluoroalkanoic acid or the anhydride thereof, in said step of obtaining C-terminal-deleted peptides." None of Covey, Vogt, Wirth, and Zeldin cure the deficiencies of Miyazaki.

Additionally, a skilled artisan would understand that the reactions disclosed by Tsugita and by Miyazaki are significantly different as follows. Tsugita requires three chemical reactions to liberate one free amino acid in one cycle (see Tsugita page 930, 2.13 C-terminal sequence). Further, the three reactions cannot occur in a single step, since the regents for each reaction react with each other when they are mixed. Therefore, it is necessary to repeat the cycle to determine some amino acids of the C-terminal.

On the other hand, the present invention needs only a single reaction to have a mixture including sequentially-processed amino acid fragments to determine some amino acids of the C-terminal.

Here, a reaction disclosed by the present application is easy to do, but requires a substantial amount of time (See Example 1 of the present application; 50 °C, 110h). A basic nitrogen-containing aromatic ring compound is used to accelerate the reaction, (See Example 2 of the present application; 60 °C, 1 h), in order to solve this problem.

Regarding the Examiner's suggestion that a skilled artisan would have combined the teachings of Tsugita and Zeldin to meet claim 20, Applicants submit that the reason to add a basic nitrogen-containing aromatic ring compound is to solve the problem that is particular to the present application. Accordingly, Tsugita and Zeldin do not disclose or suggest the function of a

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basic nitrogen-containing aromatic ring compound. And, even if Tsugita and Zeldin were

combined, the present invention cannot be reached by a skilled artisan.

Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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